The Honorable Robert S. Lasnik

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON

NORTHWEST CENTER FOR ALTERNATIVES TO PESTICIDES, *et al.* *Plaintiffs*, v. NATIONAL MARINE FISHERIES SERVICE, *Federal Defendant.*	CASE NO. 07-1791-RSL **DECLARATION OF SAMUEL D. RAUCH IN SUPPORT OF MOTION TO AMEND DKT. 50**

1. I am the Deputy Assistant Administrator for Regulatory Programs for the National Marine Fisheries Service (NMFS). In that capacity, I oversee NMFS's fisheries regulatory actions and programs, including those to support the conservation and recovery of threatened and endangered species under the Endangered Species Act (ESA). The purpose of this affidavit is to explain the background and reasons that NMFS is now requesting alteration of the settlement agreement approved by this Court on May 21, 2014 (Settlement Agreement). Specifically, NMFS is requesting alteration of the Settlement Agreement's December 31, 2017 deadline to produce a new organophosphates biological opinion for the three pesticides,

malathion, diazinon, and chlorpyrifos. NMFS requests that the Court set a deadline of December 31, 2019 for issuance of the final NMFS biological opinion. This affidavit explains the background of and reasons for this request.

2. As described further below, the preparation of the NMFS organophosphates biological opinion is part of an unprecedented inter-agency pilot effort in which NMFS, the U.S. Fish and Wildlife Service (FWS), and the Environmental Protection Agency (EPA) (the agencies) are developing a collaborative approach to resolving the complex challenges of conducting nationwide ecological risk assessments of pesticide registration that will meet the requirements of the ESA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agencies are developing a pilot consultation process that, in contrast to prior such consultations, would address the effects of pesticide registration on a nationwide basis, for all listed species, rather than on a species-by-species basis. This is an approach recommended by the National Academies of Science (NAS) that is intended to be more transparent, scientifically robust, and efficient than prior such consultations.

3. The agencies have already achieved a great deal of progress in these consultations. However, as further explained below, there are several reasons these schedule alterations are needed. Due to the sheer scope and complexity of technical issues that have arisen, the agencies need more time to assure that the process continues to move forward based on shared and collaborative methodologies and a shared basis of data and information. This process has always been conceived as an iterative, collaborative process between the agencies, with extensive input from stakeholders and the public. After an extensive public and stakeholder comment process in 2016, the EPA biological evaluations that initiated the consultation process were delayed by nine months. The inter-agency process and stakeholder input have also

identified a variety of technical and methodological issues that will require lengthier and more intensive inter-agency collaborative work to address, and that will require a more extensive process than originally anticipated. In addition, NMFS has learned that certain issues and concerns will need to be discussed concerning the basis for EPA's biological evaluations, and those evaluations are in turn one of the key foundations upon which NMFS must base any final biological opinion.

4. NMFS and FWS (the Services) are responsible for protecting species that are listed as endangered or threatened under the ESA and for protecting designated critical habitats needed for such species' survival and recovery. EPA is responsible for registering and re-evaluating pesticides under FIFRA and must ensure that pesticide use does not cause any unreasonable adverse effects on the environment. Under ESA Section 7, EPA must consult with the Services to ensure that the registration of each pesticide registration does not jeopardize any listed species or destroy or adversely modify its critical habitat.

5. For decades, there has been intensive and repeated litigation over how EPA and the Services carry out their compliance with the ESA on the EPA's pesticide registration program. Litigation continues in other courts to this day. Such litigation has included cases challenging alleged delay by in completing ESA consultations; cases challenging the results of such consultations (i.e. the Services' biological opinions); and cases alleging failures by EPA in the implementation of the Services' biological opinions. The volume of litigation, and the volume and complexity of the consultations required, has in the past threatened to create intractable gridlock.

6. The current ESA consultation process on these organophosphates represents an unprecedented and ambitious pilot effort to put ESA compliance for pesticide registrations on a

new footing. The goals of this new approach are to reduce litigation, enhance the scientific rigor of the process, increase its openness and transparency, and to allow such consultations to proceed more efficiently than has been the case for prior species-by-species consultations. It is informed by an April 30, 2013 study from the NAS entitled "Assessing Risks to Endangered and Threatened Species from Pesticides" (NAS Report). The NAS Report was prepared at the request of FWS and NMFS (collectively, the Services), EPA, and the U.S. Department of Agriculture (USDA) (collectively, the agencies).

7. ESA consultation for FIFRA pesticide registrations pose formidable scientific, logistical and methodological challenges. While pesticides are registered on a nationwide basis, ESA Section 7 requires the Services to assess risk to each individual species. Under ESA Section 7, a typical consultation focuses on a single, discrete agency action occurring at a particular time and place, and its effects on one or a few species. In contrast, EPA's pesticide registration program governs the use of over a thousand different chemicals applied throughout the United States by thousands of individual users. The ESA risk assessment for pesticide registration must determine how each chemical enters and is dispersed in a wide variety of ecological settings; under a wide variety of usage scenarios involving different cropping and agricultural systems; in widely varying environments (hydrology, climate, etc.). The assessment must consider how exposure to these chemicals affects a wide variety of biologically different kinds of non-target organisms, from micro-invertebrates to whales; it must consider how the direct and indirect effects on individual organisms affect populations and the species as a whole. The availability of data (*e.g.*, on pesticide usage, toxicity; species biology, life histories, and population dynamics) varies considerably across locales, chemicals, and species. All of these complexities give rise to many levels of scientific uncertainty.

8. There are also important differences between the analytical methods and requirements that have been developed in the past by EPA to comply with FIFRA, versus the methods used by the Services under the ESA. For example, FIFRA requires the weighing the risks posed by a pesticide with the benefits of pesticide use and use, while the ESA focuses solely on species conservation. As a result, as noted by the NAS Report, the differences between the statutes "led to conflicting approaches in evaluating risks," and made it difficult to reach a "consensus on assessing risks to listed species from pesticides." NAS Report at 3. This was due in large part to the agencies' use of "different assumptions, technical approaches (data and models used), and risk-calculation methods." NAS Report at 4.

9. The agencies requested that NAS evaluate methods for identifying the best scientific data available; evaluate approaches for developing modeling assumptions; to identify authoritative geospatial information that might be used in risk assessments; to review approaches for characterizing sublethal, indirect, and cumulative effects; to assess the scientific information available for estimating effects of mixtures and inert ingredients; and to consider the use of uncertainty factors to account for gaps in data.

10. The NAS Report concluded that "What is needed is a common, scientifically credible Approach that is acceptable to EPA and the Services." NAS Report at 4. It recommended a joint, nationwide approach, discussed the handling of models, data, and uncertainties associated with exposure analysis, considered various issues such as sublethal, indirect, and cumulative effects; modeling population-level effects; the effects of chemical mixtures; and incorporating uncertainties into the effects analysis.

11. The NAS recommended that the agencies work in a closely coordinated, collaborative fashion in order to develop and implement "a single, unified approach for

evaluating risks to listed species posed by pesticide exposure under FIFRA and the ESA." NAS Report at 33. The agencies would need to work in tandem during a three-step process. In the first step, EPA determines whether a pesticide "may affect" any listed species; in the second step, EPA determines whether it is "likely to adversely affect" a listed species, and in Step 3, the Services determine whether the chemical is likely to jeopardize listed species. Crucially, NAS found that "[i]f the Services can build on the EPA assessment conducted for Steps 1 and 2 rather than conducting a completely new analysis for Step 3, the [risk analysis] will likely be more effective and scientifically credible." NAS Report at 4. Thus, the NAS concluded that implementation of the recommended approach would require close "communication and coordination throughout the process" to "understand and reconcile the differences between how EPA assesses risk to listed species from pesticide use and how the Services reach jeopardy decisions." NAS Report at 22. Such coordination would allow at every step for "EPA's expertise in pesticides to be effectively combined with the Services' expertise in life histories of listed species and in abiotic and biotic stressors of the species." NAS Report at 27.

12. In order to implement the recommendations of the NAS Report, the agencies have engaged in extensive discussions and workshops aimed at developing shared methodologies. This process included five inter-agency workshops (in August 2013, May 2014, November 2014, January 2016, and September 2016) to address the NAS recommendations and develop the technical analyses for the EPA Biological Evaluations. The agencies also hosted a stakeholder workshop on June 29-30 with representatives of affected industry and grower groups, consultants, conservation and other non-governmental organizations, the Agencies and USDA. More information on the scientific, technical, and consultation process issues that the agencies have been addressing is available in the agencies' joint *Final Report to Congress: Endangered*

Species Act Implementation in Pesticide Evaluation Programs, December 2016 (2016 Report to Congress).

13. The Agencies worked to align existing settlements and lawsuits so that they could focus on national-level consultations for all ESA-listed species, rather than focus on single species, or a small subset of species in smaller geographical areas that were the initial focus of the ESA-related litigation. Based on recent settlement agreements as part of ongoing litigation against EPA, NMFS, and USFWS, the Agencies agreed to coordinate completion of nationwide consultations for nine pesticides: carbaryl, chlorpyrifos, diazinon, malathion, methomyl, glyphosate, atrazine, propazine and simazine. The dates provided for completion of consultation in those settlements are December 2017 for chlorpyrifos, diazinon, and malathion, December, 2018 for carbaryl and methomyl, and December 2022 for glyphosate, atrazine, simazine and propazine.

14. In 2013, the agencies issued an "Interim Approaches" proposal, under which an assessment and consultation methodology would be applied to a set of pilot nationwide consultations. This proposal was termed "interim" because it would be tested on a selected group of chemicals as a pilot, and from that experience, the agencies would gain experience and information that would allow them to revisit and refine the methods as they went forward to perform consultations on other chemicals. *See* "Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report," *available at* https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report.

15. The overarching goal of the Interim Approach was to "collaboratively develop a streamlined consultation process that meets the needs of the FIFRA/ESA workload and

integrates seamlessly [EPA's Steps 1 and 2] into [the Services] Step 3." Interim Approach at 9. The Interim Approach would be "based on shared assumptions, data, analytical processes and models, [and] will be applied collaboratively as part of EPA's Registration Review program beginning in 2014." Interim Approaches at 1. The agencies would "[d]evelop a common approach to weight of evidence analyses, using qualitative information for making the NLAA/LAA (and jeopardy) decisions." Interim Approaches at 10.

16. The ESA and its regulations do not require any public comment process in the development of biological opinions. However, the agencies recognized that the pilot consultation process should not only be collaborative and coordinated, but should also strive for transparency and make extensive use of information provided by stakeholders, the public, applicants, and other affected parties. On March 19, 2013, the agencies issued a joint document entitled "Enhancing Stakeholder Input to the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives" (EPA Docket ID Number EPA-HQ-OPP-2012-0442) (Stakeholder Proposal). The Stakeholder Proposal noted that "Because stakeholders, including state governments, universities, and growers/users, have significant amounts of relevant information and are the ultimate implementers of pesticide labels in the field, it is critical that they have a seat at the table during the development of any needed risk reduction measures to ensure that such measures are technologically and economically feasible." Stakeholder Proposal at 2. The Stakeholder Proposal outlined the following process for receiving comment on the draft biological opinions:

> Prior to formally transmitting the draft biological opinion to EPA, the Service would provide EPA and the applicant with an opportunity to identify any perceived errors in the description of the proposed action and the effects analysis (e.g., use rates, registered uses, scope of the proposed action). Subsequent to any

errors being corrected, the Service will provide EPA with the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. EPA will make this draft Biological Opinion available for public comment. All comments will be submitted to EPA, although the applicant may send a copy of its comments directly to the Service. EPA will organize all of the public comments to aid the Service in their review of the comments and will highlight comments of particular note. EPA will provide the Services with all of the comments that are submitted in response to the draft Biological Opinion.

It is anticipated that comments would focus on the analyses leading to the conclusions in the opinion, the conclusions themselves, and the reasonableness and practicality of any Reasonable and Prudent Alternatives in the draft biological opinion. This would provide another opportunity for the public to provide invaluable input on the RPAs as well as to provide/suggest/propose alternate risk reduction measures that accomplish the same protection goals that are easier/less costly for the grower/user community to implement.

During this public comment period, EPA and the Services would specifically reach out to growers to engage in what technologically and economically feasible approaches could be implemented that minimize the impact on growers and allow them to meet their pest control needs while achieving the necessary protection goals to avoid jeopardy to threatened and/or endangered species. In particular, this process should offer affected stakeholders an opportunity to provide real world data and to identify practical considerations that affect the viability of different options for mitigating risks to species. EPA will provide a key role by focusing affected entities on the availability of the draft document and timeframes for submission of input.

Upon receipt of the organized public comments from EPA, the Services will prepare a document and include it in the administration record of the consultation that details how such comments were considered and, if appropriate, how the final document was modified to address the comments. The public comments could be on the draft Biological Opinion, Reasonable and Prudent Alternatives, or Incidental Take Statement (including any comments or concerns raised by EPA that were not identified by the public). The Services will include this document in its administrative record and will provide it to EPA. Both the Services and EPA will make the document available to the public upon request.

17. As reflected in the Settlement Agreement, the agencies agreed that the first ESA consultations to implement the NAS recommendations, the Interim Approaches, and the Stakeholder Proposal, would be on the three organophosphates. The Settlement Agreement noted that "the OP biological opinion that NMFS will develop on remand should be based on new

biological evaluations that incorporate the recommendations of the NAS Report and should address impacts to all of the ESA-listed species under NMFS's jurisdiction." Settlement Agreement at 5. The agencies would "be working together on developing and testing new methodologies and a common approach." Settlement Agreement at 5. It noted that "these biological evaluations will be the first ever to address all NMFS species, and for some of NMFS's species there is far less data, information and research available than there is for salmonids." Settlement Agreement at 5.

18. Under ESA Section 7, the process of formal consultation begins when the action agency provides FWS and/or NMFS (the Services) with its evaluation of the effects of its action on ESA-listed threatened and endangered species and their designated critical habitats. For those species and habitats for which EPA concludes its action may affect, but is not likely to adversely affect, NMFS will then consider whether it can concur in that determination, which ends the consultation process for those species or habitats. For those species or habitats where EPA concludes its action is likely to adversely affect, NMFS must then prepare a biological opinion.

19. The target date in the Settlement Agreement of December 31, 2017 for completion of the organophosphates biological opinions was based on a schedule developed by the agencies under which EPA would publish draft biological evaluations out for public comment, and subsequently issue final biological evaluations to NMFS and FWS on the organophosphates by March 2016. It was on this basis that NMFS estimated completion of its biological opinion on the organophosphates by December 31, 2017, the date contained in the Settlement Agreement.

20. EPA issued draft biological evaluations for public comment on March 31, 2016, and issued a response to public comments in January 2017. *See* EPA, Response to Comments on

the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, Jan. 17, 2016, *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf (EPA Comments Response).

21. In June 2016, EPA and the Services held a two-day meeting that provided a forum for stakeholder suggestions for refining the interim methods used in the draft biological evaluations.

22. EPA received 78,000 comments on the draft biological evaluations, and identified 120 substantive comments meriting detailed review. EPA Comments Response at 2. EPA noted that "[t]he Agencies intend to refine the interim methods used in the first three pilot BEs based on a phased and iterative approach," and identified revised modeling approaches and other changes reflected in the final biological evaluations. EPA Comments Response at 2. EPA noted a number of significant issues and recommendations that had been raised that could not be fully addressed in the final biological evaluations. EPA indicated that these issues would "require further development in collaboration with the Services." EPA Comments Response at 2. These included recommendations for:

> [A] substantial reduction in the size and complexity of the assessments; a move toward more probabilistic approaches; refinements in geospatial data used to define species ranges and potential use sites; the utilization of watershed-level aquatic exposure models; improved methods for estimating exposures in riverine and estuarine/marine habitats; improved characterization and consideration of magnitude of effects; and a consideration in the timing and duration of potential pesticide exposures (e.g., linking exposure with life-history variables). Additionally, we are exploring ways to use species-specific toxicity data earlier in the first step of the [biological evaluation] process to refine, but still maintain, a protective screening process. We aim to streamline the process to a point where it is protective of species, timely for FIFRA registration review decisions, feasible within the agencies' resource constraints, and transparent to the public.

EPA Comments Response at 2.

23. The process of drafting the biological evaluations, completing a public comment process on them, and the inter-agency process where NMFS and EPA considered the public comments, has taken longer than anticipated. This was due in part to the volume of comments received, the number and complexity of the scientific and methodological issues presented, and different viewpoints among the agencies as to how to address them. Under the Interim Approaches, EPA and the Services have engaged in a significant degree of interchange and collaboration to refine the biological evaluations. The agencies have also gone to great lengths to obtain and respond to input from stakeholders as the methods are developed.

24. EPA issued final biological evaluations, thus initiating formal consultation with the Services, on January 17, 2017. This was nine months later than anticipated in the schedule that formed the basis for the Settlement Agreement's December 31, 2017 biological opinion deadline.

25. EPA's biological evaluations concluded that, with respect to species and critical habitats under NMFS's jurisdiction, its registration of the three organophosphates would adversely affect 77 listed species and 47 designated critical habitats. This includes species from a variety of regions of the United States, including turtles, salmonids, plants, sturgeon, marine fish, coral, and marine mammals. EPA also requested NMFS's concurrence with the conclusion in its biological evaluations that its action was not likely adversely affect an additional 19 listed species and three designated critical habitats under NMFS jurisdiction. EPA also initiated formal consultation at this time with FWS.

26. In April-May 2017, NMFS provided EPA with preliminary drafts of portions of its analysis for its biological opinion. On June16, 2017, EPA provided extensive comments in response, raising numerous issues and questions about NMFS's methodologies, data, and

assumptions. The comments exceeded NMFS's expectations as to the number and complexity of the issues that the agencies would need to address in working toward a coordinated, collaborative approach to the consultations.

27. As noted already, the scope and complexity of these nationwide pesticide consultations raises numerous challenges. The agencies noted in their December 2016 Report to Congress that "the interim scientific methods used to develop the Biological Evaluations including the involvement and integration of stakeholder concerns have strained existing resources of the Agencies." 2016 Report to Congress at 13-14. That Report noted that "[t]he Agencies have a finite number of staff to conduct this work and at the same time meet litigation mandated deadlines based on existing ESA-related settlement agreements." *Id*. Additionally, it noted that EPA has been sued for failure to meet its ESA obligations on new chemical registrations, potentially resulting in further resource constraints. *Id*.

28. Significant progress has been made on addressing many challenging issues. Among the accomplishments to date:

- Agency agreement on geospatial data to define pesticide use areas for agricultural and non-agricultural use patterns.
- Guidance on the construction and use of species sensitivity distributions to derive acute toxicity thresholds.
- Discussing methods for qualitative analysis of mixtures, inert ingredients, and surfactants.
- Agency agreement on aquatic habitat categories ("bins") for predicting regionally-specific aquatic exposure concentrations for each bin based on existing EPA

models, and assignment of all aquatic ESA-listed species including different life stages (e.g., juvenile vs. adult) to the appropriate bins.

- Agency agreement on the review of all registrant-submitted and open literature data for the three pilot chemicals (chlorpyrifos, malathion, and diazinon) including associated thresholds for each line of evidence and taxonomic group and associated data arrays for the three pilot chemicals.
- Agency compilation and agreement on life history data (e.g., diet, body weight, habitat, etc.) for all ESA-listed species including identification of model input parameters based on this information.
- Development of tools to advance and automate the estimation of pesticide exposures and effects for ESA-listed species for EPA's nationwide assessments.

Report to Congress at 22-23.

29. The process of issuing the NMFS draft biological opinion for public comment has also been delayed due to the change in administration in January 2017, and the time necessary for new agency leadership to be appointed by the administration and confirmed by the Senate. There has been an accompanying need to brief new leadership on these very complex analyses and processes. In addition, because this inter-agency consultation process is uniquely and unprecedentedly collaborative and coordinated, the changes in leadership at one agency affect the schedules of other agencies. So as a result, changes in leadership at EPA, FWS and the Department of the Interior have also affected NMFS's timeline because NMFS is not acting alone or unilaterally, but continually striving to coordinate and remain in step with the other agencies.

30. In recent discussions with NMFS, FWS has indicated that they will need additional time beyond December 31 to complete its biological opinions, due in large part to the need to complete a robust public process as called for in the Stakeholder Proposal. Moreover, the agencies agree that the joint public process called for in the Stakeholder Proposal will likely take longer than originally anticipated. It has always been agreed that under this coordinated agency process, FWS and NMFS would issue their biological opinions at the same time, informed by the same inter-agency and public processes.

31. During the course of the inter-agency process, the other agencies indicated to NMFS an interest in reassessing methodologies and evaluating new methodologies. As a result, the requested alterations to the schedule in the Settlement Agreement include a period of time for the agencies to consider these issues.

32. During the past month, staff from EPA, FWS, and NMFS have also been discussing timelines for providing sufficient time for NMFS and FWS to complete the desired public and stakeholder processes that would follow issuance to the public of draft biological opinions. Based on these discussions, the agencies anticipate that the public and stakeholder process would take an additional 18 months after the issuance by the Services of draft biological opinions. This 18-month period would include an opportunity for inter-agency discussions to clarify the draft biological opinion, and then a stakeholder and public input process. In the latter process, EPA would post draft biological opinions on EPA's public docket for public comment; organizing the comments, identifying key comments; and submit the comments to the Services. The Services would prepare a document responding to the comments; and the Services would then finalize the biological opinions, taking into account the information gained from these steps as appropriate. As part of the public process, EPA and the Services would seek input from

growers and other stakeholders regarding technologically and economically feasible approaches that can be implemented that minimize the impact on growers and allow them to meet their pest control needs while achieving the necessary protection goals to avoid jeopardy to threatened and/or endangered species.

33. The schedule for the process described above is somewhat longer than was originally anticipated when developing the schedules that formed the basis for the December 31, 2017 deadline reflected in the Settlement Agreement. For example, the number of issues raised by EPA regarding the preliminary draft sections of portions of the NMFS biological opinion analysis that EPA raised in June 2017 exceeded NMFS's expectations. Moreover, FWS has indicated it will require more public and stakeholder input than originally expected, and expects to work further with EPA on refining some of the data on which the risk assessments are based. The volume and substantiality of the comments received in the public comment process on EPA's biological evaluations was also greater than anticipated, and raised issues that the agencies hope to further address with the benefit of this public and stakeholder input.

34. We anticipate that FWS would follow a similar schedule to that proposed herein by NMFS, as the agencies intend to continue to move forward with a collaborative, coordinated process, as recommended by the NAS, and as further spelled out in the Interim Approaches and the Stakeholder Proposal.

35. For the above reasons, NMFS is proposing the following schedule. First, NMFS will issue to EPA a draft organophosphates biological opinion within six months from the issuance of the Court's order on this motion. During that time, the agencies would as necessary have the opportunity to continue to discuss and resolve issues raised by the other agencies regarding the methodologies underlying the consultation. Upon EPA's receipt of the draft

biological opinion, the agencies may have discussions to clarify the draft biological opinion and then would commence the stakeholder and public input process outlined above in paragraph 16. There is significant stakeholder interest in this process, as demonstrated by the 78,000 comments on EPA's draft biological evaluations and the analyses are extremely complex and technical. Given the level of interest and complexity of the issues, we cannot provide precise time estimates for the various processes identified in paragraph 16, but we estimate that NMFS and EPA will be able to conclude this process in sufficient time to allow NMFS to issue its final biological opinion by December 31, 2019. NMFS's biological opinion must be based on the administrative record before the agency, and if information is modified or augmented by EPA, NMFS must take those changes into account.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this ninth day of November 2017.

Samuel D. Rauch, III
Deputy Assistant Administrator for Regulatory Programs
National Marine Fisheries Service